

Application No.: 10/603229  
Docket No.: CL1127USDIV

RECEIVED  
CENTRAL FAX CENTER  
FEB 15 2007

Page 4

**REMARKS**

Claims 32 - 36 are under consideration in this application. The claims are rejected variously under 35 USC § 112 and 103

Claims 32-36 have been canceled by this amendment

Claims 52-53 have been added. New Claim 52 contains the limitations of original claims 32 and 33. New claim 53 contains the limitations of original claims 32 and 36.

No new matter has been added

**Specification**

The specification is objected to as the recitation of US 09/442021 on page 1 has not been updated. The specification has been amended to overcome this objection.

**Claim Rejections - 35 USC § 112**

Claims 32-36 are rejected under 35 USC § 112 2d paragraph for indefiniteness.

Claims 33 - 36 are rejected as they recite the limitation "The binary transgenic viral expression system of Claim 32", however there is no antecedent basis for this limitation in Claim 32.

Claims 32 - 36 are canceled. New claim 52 recites the limitations of original claims 32 and 33. Applicants submit the rewriting of these claims overcomes this rejection for lack of antecedent basis

Claims 33-36 contain the recitation of the phrase "binary transgenic expression system" which is not defined in the specification.

Claims 33-36 have been re-written as described above. The phrase "binary transgenic expression system" no longer is a limitation in the new claims. As such, this rejection is overcome.

Claim 35 is rejected for the recitation "PI-HC-Pro, HC-Pro, and 2b protein" which makes the claim unclear. These limitations of claim 35 are now found in claim 52 and have been clarified according to the examiner's suggestions.

Claim 32 is found to be indefinite because it is unclear if the blocking fragment of (i) is inserted into the suppressor of (ii) or the suppressor of (ii) is within the blocking fragment of (i). Additionally it is not clear how the site-specific recombination activates the suppressor gene. Applicants traverse. Applicants submit that the claims reflect the description in the specification and as such as clear as written.

The limitations of Claim 32 are now found in new claims 52-53. A description of the present embodiment of the invention involving the co-expression of a silencing suppressor and the activation of the inactive replicon is found on page 37, beginning on line 32 through page 38, line 33, of the specification and Figure 1. An inactive replicon is a genetic element that is incapable of replication without activation by some other event. (see definition on page

Application No.: 10/603229  
Docket No.: CL1127USDIV

Page 5

23, line 15) In one embodiment of the invention activation may be effected by release of the replicon from the chromosome to allow for episomal replication (Page 23, line 15 of the specification).

Addressing the examiner's specific questions, the inactive replicon serving as a blocking fragment is neither inserted into nor inserted by the suppressor gene. As illustrated in Figure 1, the inactive replicon (segment B), is upstream of the suppressor gene and downstream of a promoter driving a target gene. Excision of the inactive replicon releases it for episomal replication and allows the promoter to drive expression of the suppressor gene.

Claims 32-36 are rejected under 35 USC § 112, 1<sup>st</sup> paragraph for lack of written description and for lack of enablement. The examiner finds that the claims are broadly drawn to a genera of any silencing suppressors and inactive replicons, however finds that the specification only describes and enables PI-HC-Pro, HC-Pro, polypeptides of Tobacco Etch Virus and 2b protein of Cucumber Mosaic Virus as silencing suppressors in plants and inactive replicons from Gemini viruses and single strand RNA viruses (paragraphs 5 and 6 of the present action)

Claims 32-36 have been canceled in favor of new claims 52-53. New claims 52-53 limit the inactive replication to those derived from a virus selected from the group consisting of Gemini viruses and single strand RNA viruses and where the suppressor is selected from the group consisting of PI-HC-Pro, HC-Pro, polypeptides of Tobacco Etch Virus and 2b protein of Cucumber Mosaic Virus. In view of these amendments applicants submit that the claims comply with all aspects of 35 USC § 112 and respectfully request withdrawal of this rejection.

#### ***Claim Rejections – 35 USC § 103***

The examiner presumes that the subject matter of the claims under consideration here were commonly owned at the time the invention was made. The examiner's presumption is correct.

Claims 32 and 35 are rejected under 35 USC § 103(a) as being unpatentable over Lloyd et al (1994, *Mol. Gen. Genet.* 242:653-657), herein after "Lloyd", in view of Brigneti et al (1998, *The EMBO Journal*, 17:6739-46), hereinafter "Brigneti".

Lloyd is cited for teaching FLP/FRT recombination systems in transformed tobacco plants, where these recombination regions flank a blocking sequence placed between a promoter and a transgene. Lloyd does not teach a silencing repressor gene.

Brigneti is cited for teaching HC-Pro, polypeptides and 2b protein of Cucumber Mosaic Virus suppress gene silencing in the expression of a GFP reporter.

Application No.: 10/603229  
Docket No.: CL1127USDIV

Page 6

It is the examiner's view that the skilled person would be motivated to use the methods of Lloyd using the suppressor genes of Brigneti to derive the present invention. Applicants traverse.

It is axiomatic that in order to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

The claims as re-written contain the limitations of both a silencing suppressor and an inactive replicon as a blocking fragment. Neither Lloyd nor Brigneti teach the use of an inactive replicon as a blocking fragment or its use in regulated gene expression. As such the combined references do not teach all the limitations of the invention as now claimed and thus do not render the invention obvious. In view of the foregoing applicants submit that the claims as now amended comply with all the requirements of 35 USC § 103 and respectfully request withdrawal of this rejection.

#### ***Double Patenting***

Claims 32-35 are rejected on the ground of non-statutory obviousness-type double patenting over claim 14 of US 6632980 in view of Brigneti.

A timely filed terminal disclaimer may be used to overcome this rejection.

Applicants have filed herewith a terminal disclaimer disclaiming the terminal portion of any patent that grants on the present application that would extend beyond the statutory term of US 6632980. In view of the filing of this terminal disclaimer applicants submit this rejection is overcome.

#### ***Conclusion***

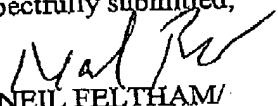
Applicants note the examiner finds that original claims 33, 34, and 36 are free of the prior art due to the failure of the prior art to teach an inactive viral replicon as a blocking sequence and BL1 or BR1 as silencing suppressors. As the claims as now amended recite either of these limitations applicant submit that all claims are now free of the art and respectfully request allowance of the claims as amended.

Application No.: 10/603229  
Docket No.: CL1127USDIV

Page 7

Should there be any fee due in connection with the filing of this Response and Amendment please charge such fee to Deposit Account No. 04-1928 (E. I. du Pont de Nemours and Company).

Respectfully submitted,

  
/S. NEIL FELTHAM/

S. NEIL FELTHAM

ATTORNEY FOR APPLICANTS

Registration No.: 36,506

Telephone: (302) 992-6460

Facsimile: (302) 992-5374

Dated: February 14, 2007